SPECIFICATION AMENDMENTS

Immediately before paragraph [0034] of the specification, please amend the heading to read:

~~DETAILED~~ BRIEF DESCRIPTION OF THE ~~INVENTION~~ DRAWINGS

~~Brief Description of the Drawing~~

Immediately before paragraph [0040], please amend the heading to read:

~~Discussion~~ DETAILED DESCRIPTION OF THE EMBODIMENTS

Please amend the following paragraphs of the specification:

[0003] Most balloon catheter uses require means for delivering a therapeutic payload (the most notable exception being coronary angioplasty wherein the expansion of the balloon itself elicits the desired therapeutic effect), be it radiation, a drug, cold, RF energy, etc., to the target site. For example, to ablate an area of a vessel in a patient's body, RF energy must be delivered from its source, usually outside the patient's body, to specific locations on the balloon that is situated at the target site. Means for achieving this include having thin conductive metal electrodes displayed in a desired pattern on the outer surface of the balloon and using the patient's body as the second electrode or ground. Alternatively, the balloon itself may be rendered energy-transmissive by doping the material from which it is made with a conductive metal or other ~~conducive~~ conductive substance. A non-conductive mask is then applied to a surface of the conductive balloon to create the desired ablation pattern. Numerous other ways of creating ablation balloons are known in the art. All of them are generally relatively complicated to manufacture and tend to be quite expensive.

[0027] ~~In~~ In an aspect of this invention, the conductive areas of the balloon have a wall thickness of from about 0.0005" to about 0.005".

[0040] In Fig. 1A, catheter shaft 9 has a distal section 12 which contains deployable balloon 10, a shaft distal end 2 a shaft proximal end 3 and at least one lumen 13 extending between the two ends. Lumen 13 has at least one opening at the distal section 12 of the catheter shaft 9. Handle 4 is located at the proximal end of catheter shaft 9. The handle may contain means for controlling the movement of distal section 12 of shaft 9. Handle 4 may also include one or more hollow tubes 7, each having a proximal end, a distal end, a passageway and a locking valve 8 attached to it. Each such passageway is connected to one of the lumens 13 and is used to deliver and receive substances, in particular a working fluid for the inflation of the balloon when deployed, to and from distal section 12. In general, a balloon catheter has at least two lumens 13, one for inflation of the balloon and one for deflation of the balloon. In the case of an ablation balloon catheter, additional passageways and/or lumens are required for passage of wires from an RF generator, usually located remote from the catheter and connected thereto by electrical wires, to electrodes located at balloon 10. At the distal end of section 12 is a guide wire lumen 19 through which guide wire 18 is passed. Figure 1B shows a balloon deployed and inflated. Balloon 10 is shown with a conductive region 14 and a non-conductive region 17, as would be the case when the balloon catheter is used for ablation. In this case, the working fluid used to inflate the balloon is usually physiological saline, which is conductive and compatible with body fluids. A ground electrode is attached to a remote location in the patient's body, conductive region 14 is placed in contact with tissue to be ablated and RF energy is transmitted to the saline by wire/electrode 20 which is attached to an energy

source at its other end, and then through the ~~conducive~~ conductive region 14 to the tissue. It is understood that depiction of the balloon as an ablation device is for illustrative purposes only and is not intended, nor is it to be construed, as limiting the invention in any way.

[0041] In one aspect of this invention, the balloon of the balloon catheter is constructed of a polymeric substance that is hydrophilic. By hydrophilic, it is meant that the polymer, when in contact with an aqueous solution, can absorb a quantity of water into it's structure while still maintaining its structural integrity. When the polymer absorbs water, it is said to be hydrated. To be useful as a balloon-forming material of this invention, the hydrophilic polymer must have sufficient strength to maintain structural integrity even when the balloon is subjected to substantial internal pressure as from a working fluid, usually physiological saline, used to inflate it and to external forces such as abrasion that might occur on contact with the interior surfaces of a patient's vessels. Thus, in a presently preferred embodiment of this invention, the hydrophilic polymer must have an ultimate tensile strength, both dry and in the hydrated state, of at least 3000 psi. As used herein, tensile strength has its usual meaning, that is, the force, measured in pounds per square inch (psi) needed to stretch the polymer until it breaks.

[0042] Balloons of this invention can be constructed by any of the various techniques well-known to those skilled in the art. For example without limitation, the polymer can be dip-coated on a mandrel that has a defined size and shape. When removed from the mandrel, the balloon, when inflated with about one atmosphere of pressure will assume the dimensions of the mandrel without incurring any tensional force in the polymer. ~~This condition, the shape and~~ The dimensions of a balloon inflated with about one atmosphere

pressure after formation by whatever means selected will, for the purpose of this discussion, be called the balloon's equilibrium dimensions.

[0043] Balloons of this invention may also be formed by spin-coating in a hollow mold. When the mold is removed, as in the case of a dip-coated mandrel, the balloon will inflate to equilibrium dimensions that are the same as the interior dimensions of the hollow mold.

[0046] In addition to tensile strength, in a presently preferred embodiment of this invention, the polymeric material of which a balloon is made ~~had~~ has sufficient elasticity so as to be capable of stretching substantially beyond its equilibrium dimensions without failing[[,]]; that is tearing or bursting, when subjected to internal pressures greater than one atmosphere. Classically, elasticity is a measure of the ability of a material to stretch under tension to beyond its initial dimensions and then to return to, or nearly to, its original dimensions when the tension is relaxed. While the polymers used to make the balloon of this invention may react in the classical manner and, as such, are within the scope of this invention, such is not necessarily the case. That is, a balloon of this invention may be capable of inflation up to 400% of its equilibrium dimensions but may not return to, or even nearly to, its equilibrium dimensions when deflated and may in fact remain substantially "stretched out." It is presently preferred that the hydrophilic polymer selected for balloons of this invention be such that the balloon is capable, when hydrated, of up to 50% expansion beyond its equilibrium dimensions. When being inflated, a balloon of this invention will expand in such a manner that all its dimensions increase in approximately a constant ratio to the corresponding equilibrium dimension; that is, as it is inflated the balloon essentially retains its initial equilibrium shape – it just gets bigger.

[0049] In another aspect, a balloon of this invention is intended for use in an ablation balloon catheter. For this use, a non-conductive mask is applied to a surface of the conductive hydrophilic balloon to create a pattern for ablation. Such a masked balloon is shown in Fig. 2. Balloon 105 has distal-facing surface 112 and proximal-facing ~~suface~~ surface 111. Proximal catheter shaft 100 protrudes from the proximal end of balloon 105 while catheter tip 101 protrudes from the distal end of balloon 105. The non-cross-hatched portions 110 of the surface of balloon 105 are non-conductive by virtue of a mask adhered to a surface of the balloon. The mask may be adhered to the outer or inner surface of the balloon. Cross-hatched portion 120 of the surface of balloon 105 [[.]] is the conductive region. When the distal end of balloon 105 is inserted in a vessel such as the pulmonary vein of a patient from within the heart, region 120 is pressed up against the heart wall at the ostium or opening from the heart into the vein. A ground electrode is attached to a remote location on the patients body and then an RF signal is generated at the proximal end of the catheter proximal to section 100 of the catheter shaft (usually at a generator attached to the catheter in the vicinity of the handle) and is transmitted through wire 131 to electrode 130. The signal is conducted through region 120 of the balloon and a circuit is completed so that RF energy is delivered to the tissue in contact with region 120 and is thereby ablated.

[0051] A wide range of non-conductive polymers can be used to create masks compatible with a TECOPHILIC® balloon. For example, without limitation, when the TECOPHILIC® balloon is formed by the dip-molding method, a presently preferred mask polymer is TECOFLEX® SG-85A, also manufactured by Thermedics Polymer Products. TECOFLEX®, like TECOPHILIC®, is a polyether-based aliphatic polyurethane and therefore is very compatible with TECOPHILIC® chemically so that masks formed from TECOFLEX®

adhere well to surfaces made of TECOPHILIC®. In addition, the TECOFLEX has an ultimate tensile strength and elongation that is compatible with the TECOPHILIC. Other matching TECOFLEX® and TECOPHILIC® family ~~member~~ members useful for making the balloons of this invention will become apparent to those skilled in the art based on the disclosure herein and are within the scope of this invention.

[0053] If desired, the surface of the ~~TECOPHILIC®~~ TECOPHILIC® balloon can be pre-treated to assist in prevention of bead formation during film formation and to enhance adhesion and coating uniformity. For example, without limitation, the surface of the TECOPHILIC® balloon can be subjected to an Argon plasma prior to coating.

[0056] In Fig. 3, balloon 300 is shown inflated in the locus of the ostium 310 of a vessel 320 in a patient's body. Balloon 300 consists of a first diameter 302, a second diameter 304 and a third diameter 306. Diameter 306 is smaller than either diameter 302 or diameter 304. Diameters 302 and 304, on the other hand, can be the same or different. In a presently preferred embodiment of this invention diameter 304 is less than diameter 302 (and diameter 306 is less than either of the other two). The catheter shaft 330, having distal end 335 and proximal end 337 is inserted into the vessel prior to inflation of the balloon. As the balloon inflates, the segment having diameter ~~302~~ 304 expands and presses against wall 322 of vessel 320, causing it to dilate. The tissue 380 at the proximal side of the ostium is, in most circumstances, thicker than and therefore less elastic than the tissue of the wall 322 of the vessel. Thus, as the portion of balloon 300 having diameter 304 is increased by inflation of the balloon, the pressure of proximal-facing sloped surface 340 against wall 322 pulls distal-facing sloped surface 350 into intimate contact with tissue 380 in the vicinity of the ostium and holds it there thus relieving the operator of the chore of

manually maintaining pressure on the balloon. This is at times referred to herein as self-anchoring of the balloon.

[0057] For the purpose of illustration only, the balloon is shown as an ablation balloon. That is, the distal-facing sloped surface 350 is shown as having an energy-conductive band 380 that contacts tissue around the ostium. The ~~remainer~~ remainder of the balloon is masked by a non-conductive polymer. Upon delivery of RF energy to the energy conductive region of the balloon, the contacted tissue is ablated. It is understood, however, that region 380 or, in fact, any or all portions of distal-facing sloped surface 350 that is in intimate contact with tissue may constitute a therapeutic element. That is, a drug could be diffused through surface 350 and infused into the tissue, and radioactive beads could be removably adhered to surface 350 and transferred to the tissue, etc. In all these applications, the segment of the balloon having diameter 304 maintains the contact necessary to obtain the desired effect.